Editorials

A New Look in Government Regulation?

SOME SORT OF REGULATION OR GOVERNANCE is essential if any complex system with many interdependent parts is ever to work smoothly—or at all. This is true of inanimate as well as animate systems. And it is true of human societies and of human systems within these societies. Health care is such a complex system within our own human society. But a satisfactory approach to its regulation and governance still eludes us. Certainly most of the efforts to regulate health care have created more problems than they solved, and almost no one has been satisfied with the results.

In the Medical News section of the October 25, 1985, issue of the *Journal of the American Medical Association (JAMA)*[1] there are a number of statements or reports concerning the present functions of the Food and Drug Administration (FDA) and how it prepares to "meet the regulatory challenges of the 21st century." One cannot help but be impressed with the extent of the FDA's interactions with other federal organizations ("working with virtually every federal agency") and with state and local governments, and its effect on almost every segment of the private sector in one way or another. Its charge, of course, is to protect the quality of the food we eat and of the drugs and medical devices that we use in health care. Significantly, its responsibilities fall short of health care delivery itself. Also, one can be even more impressed by what appears to be an evolutionary, perhaps even revolutionary, change in attitude in the agency toward developing and enforcing regulations. To be sure, the power of the federal government is still there, but there is an evident effort to be more closely in touch with the professions and the public, to seek and accept advice from them, and to use education of the profession, the public and others, along with reasonable regulations, to achieve the aims of the agency. The shift seems to be a softening of what has often been more of an adversarial approach in imposing and enforcing government regulations, toward more emphasis on genuine collaboration to achieve recognized common goals. In theory at least, this should result in better, more workable and more acceptable regulations from the FDA. One even senses that this more collaborative approach may even now be coming into place and beginning to work.

The food, drugs and medical devices regulated by the FDA and health care delivery have much in common. Both are complex technologic and social systems involving the health and well-being of individual citizens, and both interact with "virtually every federal agency," with state agencies, and in one way or another affect almost every segment of the private sector. And it is to be noted that both are at the cutting edge of modern society's still stumbling efforts to find ways of dealing with the complex and irreversible social, economic and political interdependencies that have been the inevitable result of the scientific and technologic advances that have occurred most particularly in recent decades.

Now let it be clear that this author in no way believes that health care should be given to the FDA to regulate. But the approach and activities of the FDA as described in the *JAMA* reports do suggest that the FDA may be on to something with its new, more collaborative approach toward necessary government regulation of the food and drug industry. Government regulation of health care delivery has so far been distinctly adversarial in tone, has been distinctly inefficient and costly and, in addition, has not been particularly successful in achieving its goals. Maybe the health care regulators should consider the new FDA approach, borrow a page from the FDA book and at least try a little more collaboration with the health professions, the autonomous and still relatively independent health care agencies and institutions, and with the public, both sick and well. This just might be the wave of the future for needed regulation of essential services in an increasingly interdependent society that is also dedicated to maintaining a maximum degree of freedom and independence for its individual citizens and for its interdependent component parts.

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REFERENCE

1. FDA prepares to meet regulatory challenges of the 21st century (Medical News). JAMA 1985 Oct 25; 254:2189-2202

Breast Cancer Detection

DATA CONTINUE TO ACCUMULATE supporting the potential reduction in breast cancer mortality by intensive screening. Improvements in mammographic technique can significantly reduce the radiation risk,[1] which may in fact be nonexistent for women over age 40 (according to A.B. Miller, MB, FRCP, Epidemiology Unit, National Cancer Institute of Canada [oral communication]). Screening clinics are opening across the country. The article by Margolin and Lagios in this month's journal shows that early detection using mammography is not a capability confined to the teaching hospitals but can be accomplished in a community setting if a thoughtful, carefully monitored program is developed. If screening is to result in reduced mortality, it requires this kind of carefully supervised approach using the highest quality mammography.

In the early 1960s a landmark screening study was undertaken by the Health Insurance Plan of New York (HIP) in which more than 60,000 women were randomly assigned into two groups. Half of the women were offered annual screening by physical examination and mammography for four years.[2] This study group was compared with the unscreened control population and in a 10- to 14-year follow-up a 25% to 35% mortality reduction was shown for women in the screening group.[3] The results of the HIP study led to the Breast Cancer Detection Demonstration Project (BCDDP) in the early 1970s in which more than 275,000 women underwent physical examination and mammographic screening in 27 centers across the United States. As the authors point out, the BCDDP showed the enhanced ability of modern x-ray mammography to detect a significant number of nonpalpable malignant lesions. These clinically occult tumors are usually